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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,634	07/23/2003	Gunther Bellmann	P02819-C1	8078

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Bausch & Lomb Incorporated
One Bausch & Lomb Place
Rochester, NY 14604-2701

EXAMINER

BERKO, RETFORD O

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,634

Applicant(s)

BELLMANN ET AL.

Examiner

Relford Berko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/23/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DTAILED ACTION

Acknowledgement: The Information Disclosure Statement and preliminary amendment filed July 23, 2003 is acknowledged.

Status of Claims

Claims 1-15 are cancelled in view of applicant's amendment. Claims 16-39 are pending following the amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (WO 94/15597) in view of Schoenwald et al (US 4, 271, 143) further in view of Goldenberg et al (WO 94/10976).

The claims are directed toward an ophthalmic composition comprising a free-flowing vehicle with increased viscosity, a preservative consisting essentially of

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benzyl lauryldimethylammonium salt (i.e. chloride); in the form wherein the vehicle is a gel, a single-phase aqueous solution or dispersion and the polymer is carboxyvinyl polymer, carboxymethylene polymer, cellulose derivative or dextran derivative. The claims are also drawn toward the ophthalmic composition wherein the vehicle is a two-phase liquid or oil/water emulsion and the composition having a preservative, a pharmaceutically active ingredient, tonicity adjusting agent or pH agent so that the composition is maintained a physiologically acceptable pH and does minimum irritation or damage to the eye tissue even if applied for a lengthy period of time.

Wong et al (WO '597) discloses an ophthalmic composition comprising benzyl lauryldimethylammonium chloride comprising flubiprofen as active agent in solution (abstract, page 3, lin 27 and page 4, lin 5) having pH of about 6.4-6.6 (Table 1 at page 6).

Patent '597 does not disclose the use of carboxyvinyl polymer, does not disclose carbopolymethylene polymer and does not disclose the use of oil/water emulsion or gel in the ophthalmic composition having preservatives and tonicity enhancers.

Schoenwald et al (Patent '143) discloses the an ophthalmic composition in the form of a gel containing a drug as a drug/polymer dispersion (col 2, lin 5-25) having physical characteristics such as plastic viscosity and rheology making it free-flowing (col 2, lin 35-50). Patent '143 discloses the use of carboxypolymethylene polymer (a carboxy vinyl polymer; col 2, lin 56-60). According to Schoenwald et al, the composition is a hydrogel having pH 4.5-8.5 (col 3, lin 30-40), the gel formulation has prolonged activity two to three times when compared to aqueous solutions (col 4, lin 1-5, col 7, lin 30-40); possess slow release which can be used for

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various diseased conditions of the eye and the composition is clear so that the vision is not blurred (col 7, lin 15-20 and lin 35-40).

Goldenberg et al (Patent WO '976) discloses an ophthalmic drug delivery system comprising drugs for treating eye conditions (abstract and page 3-4). Patent '976 discloses increased viscosity, discloses the use of preservatives, stabilizers and tonicity enhancers; the daily dosage of which depends on the individual patient's condition and particular ophthalmic ailment and disease state. (page 5).

One of ordinary skill in the art would have been motivated to make an ophthalmic formulation comprising of a drug, a carrier such as benzyl lauryldimethylammonium chloride and include in the formulation a suitable polymer such as carboxypolymethylene and other ingredients such as active agents, preservatives and tonicity enhancers. The motivation to combine the cited references is based upon the advantage disclosed in Patent '143 that the gel formulation in Patent 143 remains in the eye for a period of 4-8 hours compared to prior formulations and as such, the disclosures in the cited prior art; one of ordinary skill would have expected reasonable success in obtaining an ophthalmic composition that would have suitable characteristics permitting prolonged retention and slow release to the diseased eye that suits the individual patient's needs and disease condition. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill at the time it was made.

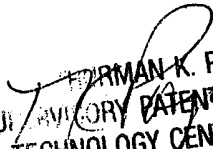
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 703-305-4442. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


THURMAN K. PAGE
SUI PER VICTORY PATENT EXAMINER
TECHNOLOGY CENTER 1600